

DECLARATION AND POWER OF ATTORNEY
Original Application

As below named inventor, I declare that I have reviewed and understand the contents of the specification, including the claims, as amended by any amendment specifically referred to in this Declaration, that the information given herein is true, that I believe that I am the original, first and joint inventor of the invention entitled:

**DIAGNOSTIC USE OF POLYMORPHISM IN THE GENE CODING FOR
TNF RECEPTOR II AND METHOD FOR DETECTING
NON-RESPONDERS TO ANTI-TNF THERAPY**

XX the attached specification or

the specification in application Serial No. 09/ _____ filed (date) _____ and that I acknowledge my duty to disclose information in accordance with 37 C.F.R. Section 1.56 and defined on the attached sheet, which is material to the examination of this application, that I do not know and do not believe the same was ever known or used in the United States of America before my or our invention thereof or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to this application, that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application and that as to applications for patent or inventor's certificate filed by me or my legal representatives or assigns in any country foreign to the United States of America, the earliest filed foreign application(s) filed within twelve months prior to the filing date of this application and all foreign applications filed more than twelve months prior to the filing date of this application, if any, are identified below.

CHECK APPROPRIATE BOX:

no earlier-filed foreign applications.

XX Required information as to foreign applications filed prior to the filing date of this application is attached hereto and made a part hereof:

Attorney Docket No.
25481- P001US

PATENT APPLICATION

POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

| <u>NAME</u> | <u>REGISTRATION NO.</u> |
|----------------------|-------------------------|
| James J. Murphy | 34,503 |
| Kelly K. Kordzik, | 36,571 |
| Ross Spencer Garsson | 38,150 |
| Barry S. Newberger | 41,527 |

SEND CORRESPONDENCE TO:
WINSTEAD SECHREST & MINICK
5401 Renaissance Tower
1201 Elm
Dallas, Texas 75270

DIRECT TELEPHONE CALLS TO:

James J. Murphy, Esq.
(214) 745-5374
Fax: (214) 745-5390

Winstead Sechrest & Minick, P.C.'s customer number is 23-2426.

| | | | | |
|-----------------------------------|--|--|-----------------------------------|----------|
| (201) FULL NAME OF INVENTOR | LAST NAME Schreiber | FIRST NAME Stefan | MIDDLE NAME | |
| RESIDENCE & CITIZENSHIP | CITY Kiel | STATE OR FOREIGN COUNTRY Germany | COUNTRY OF CITIZENSHIP Germany | |
| Post OFFICE ADDRESS | POST OFFICE ADDRESS Moltke Strasse 77 | CITY D-24105 Kiel | STATE OR COUNTRY Germany | ZIP CODE |
| (202) FULL NAME OF INVENTOR | LAST NAME Hampe | FIRST NAME Jochen | MIDDLE NAME | |
| RESIDENCE & CITIZENSHIP | CITY Berlin | STATE OR FOREIGN COUNTRY Germany | COUNTRY OF CITIZENSHIP Germany | |
| Post OFFICE ADDRESS | POST OFFICE ADDRESS Heidekampweb 4 | CITY D-12437 Berlin | STATE OR COUNTRY Germany | ZIP CODE |
| (203) FULL NAME OF INVENTOR | LAST NAME Mascheretti | FIRST NAME Silvia | MIDDLE NAME | |

Attorney Docket No.
25481- P001US

PATENT APPLICATION

| | | | | |
|-------------------------------|--|--|---------------------------------|----------|
| RESIDENCE & CITIZENSHIP | CITY Kiel | STATE OR FOREIGN COUNTRY Germany | COUNTRY OF CITIZENSHIP Italy | |
| POST OFFICE ADDRESS | POST OFFICE ADDRESS Stern Strasse 9 | CITY D-24103 Kiel | STATE OR COUNTRY Germany | ZIP CODE |

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

| | | |
|----------------------------------|-----------|------|
| Name (201) Stefan Schreiber | Signature | Date |
| Name (202) Jochen Hampe | Signature | Date |
| Name (203) Silvia Mascheretti | Signature | Date |

::ODMA\PCDOCS\Dallas_1\3502887\1

Section 1.56 Duty to Disclose Information Material to Patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by Sections 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applications to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the application takes in:

(i) opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of patentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any considerations given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

Attorney Docket No.
25481- P001US

PATENT APPLICATION

© Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;
(2) Each attorney or agent who prepares or prosecutes the application;
and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor.

::ODMA\PCDOCS\Dallas_1\3502887\1
233:25481- P001US

09902176-071001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Schreiber, et al.
Filing date: July , 2001
Art Unit: not yet assigned
Examiner: not yet assigned
Title: DIAGNOSTIC USE OF POLYMORPHISMS IN THE GENE CODING
FOR THE TNF RECEPTOR II AND METHOD FOR DETECTING
NON-RESPONDERS TO ANTI-TNF THERAPY

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

DESIGNATION OF DOMESTIC REPRESENTATIVE

I, Stefan SCHRIEBER, Jochen HAMPE, and Silvia MASCHERETTI, inventors of the above-captioned patent application, does hereby appoint James J. Murphy, Kelly K. Kordzik, Ross S. Garsson and Barry Newberger, all of the firm of WINSTEAD SECHREST & MINICK P.C. to be its domestic representative on whom may be served notices or process in proceedings affecting this application and any subsequent issued patent.

Please address all correspondence to:

James J. Murphy
Winstead Sechrest & Minick P.C.
P.O. Box 50784
1201 Main Street
Dallas, Texas 75250-0784
(214) 745-5374

Respectfully submitted,

Dated: _____

By: _____
Stefan Schreiber

Dated: _____

By: _____
Jochen Hampe

Dated: _____

By: _____
Silvia Mascheretti

| | | |
|---|-------------------------------|--------------|
| DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing OR <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required) | Attorney Docket Number | 25481-P001US |
| | First Named Inventor | Schreiber |
| | COMPLETE IF KNOWN | |
| | Application Number | / |
| | Filing Date | |
| | Group Art Unit | |
| | Examiner Name | |

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Diagnostic Use of polymorphisms in the Gene Coding for the TNF Receptor II and Method for Detecting Non-Responders to Anti-TNF Therapy

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) [] as United States Application Number or PCT International

Application Number [] and was amended on (MM/DD/YYYY) [] (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attached? | |
|-------------------------------------|---------|----------------------------------|--------------------------|--------------------------|-------------------------------------|
| | | | | YES | NO |
| 00114786.7 | Europe | 07/10/2000 | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

[Page 1 of 2]

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

| | | | |
|---|----------------|---|----------------|
| Direct all correspondence to: <input checked="" type="checkbox"/> Customer Number or Bar Code Label | | <input type="checkbox"/> OR <input type="checkbox"/> Correspondence address below | |
| Name James J. Murphy WINSTEAD SECHREST & MINICK P.C. | | | |
| Address P.O. Box 50784 1201 Main Street | | | |
| City | Dallas | State | Texas |
| ZIP | 75250-0784 | | |
| Country | US | Telephone | (214) 745-5374 |
| | | Fax | (214) 745-5390 |
| I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. | | | |
| NAME OF SOLE OR FIRST INVENTOR : | | <input type="checkbox"/> A petition has been filed for this unsigned inventor | |
| Given Name (first and middle [if any]) | Stefan | Family Name or Surname | Schreiber |
| Inventor's Signature | | | Date |
| Residence: City | Kiel | State | |
| | | Country | DE |
| | | Citizenship | |
| Mailing Address Moltkestrasse 77 | | | |
| City | D-24105 Kiel | State | |
| | | ZIP | |
| | | Country | Germany |
| NAME OF SECOND INVENTOR: | | <input type="checkbox"/> A petition has been filed for this unsigned inventor | |
| Given Name (first and middle [if any]) | Jochen | Family Name or Surname | Hampe |
| Inventor's Signature | | | Date |
| Residence: City | Berlin | State | |
| | | Country | DE |
| | | Citizenship | |
| Mailing Address Heidekampweg 4 | | | |
| City | D-12437 Berlin | State | |
| | | ZIP | |
| | | Country | Germany |
| <input checked="" type="checkbox"/> Additional inventors are being named on the <u>1</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto. | | | |

PLEASE SIGN
& DATEPLEASE SIGN
& DATE

Please type a plus sign (+) inside this box → ☐

PTO/SB/02A (11-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S)

Supplemental Sheet

Page 1 of 1

Name of Additional Joint Inventor, if any:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Silvia

Mascheretti

Inventor's
Signature

Date

Residence: City

Kiel

State

Country

Germany

Citizenship

Mailing Address Sternstrasse 9

Mailing Address

City

D-24103 Kiel

State

ZIP

Country

Germany

Name of Additional Joint Inventor, if any:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Inventor's
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

Mailing Address

City

State

ZIP

Country

Name of Additional Joint Inventor, if any:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any))

Family Name or Surname

Inventor's
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

Mailing Address

City

State

ZIP

Country

Burden Hour Statement: This form is estimated to take 21 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PLEASE SIGN
& DATE

0990216-01001

Please type a plus sign (+) inside this box ☐

PTO/SB/81 (02-01)

Approved for use through 10/31/2002. OMB 0651-0035

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it display a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

| | |
|------------------------|------------------------------|
| Application Number | |
| Filing Date | |
| First Named Inventor | Stefan Schreiber |
| Title | Diagnostic Use of Polymorphi |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 25481-P001US |

I hereby appoint:

☐ Practitioners at Customer Number

☒ Practitioner(s) named below:

| Name | Registration Number |
|----------------------|---------------------|
| James J. Murphy | 34,503 |
| Kelly K. Kordzik | 36,571 |
| Ross Spencer Garsson | 38,150 |
| Barry Newberger | 38,286 |

Place Customer
Number Bar Code
Label here

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please change the correspondence address for the above-identified application to:

☐ The above-mentioned Customer Number.

OR

☐ Practitioners at Customer Number

OR

Place Customer
Number Bar Code
Label here

| | | | | | |
|---|----------------------------------|-------|----------------|-----|------------|
| <input checked="" type="checkbox"/> Firm or Individual Name | James J. Murphy | | | | |
| Address | Winstead Sechrest & Minick P.C. | | | | |
| Address | P.O. Box 50784, 1201 Main Street | | | | |
| City | Dallas | State | Texas | Zip | 75250-0784 |
| Country | United States of America | | | | |
| Telephone | (214) 745-5374 | Fax | (214) 745-5390 | | |

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

| | |
|-----------|------------------|
| Name | Stefan Schreiber |
| Signature | |
| Date | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

09902176-071001

PLEASE SIGN
& DATE

Please type a plus sign (+) inside this box → ☐

PTO/SB/81 (02-01)

Approved for use through 10/31/2002. OMB 0651-0035

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

| | |
|------------------------|------------------------------|
| Application Number | |
| Filing Date | |
| First Named Inventor | Stefan Schreiber |
| Title | Diagnostic Use of Polymorphi |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 25481-P001US |

I hereby appoint:

☐ Practitioners at Customer Number

OR

☒ Practitioner(s) named below:

| Name | Registration Number |
|----------------------|---------------------|
| James J. Murphy | 34,503 |
| Kelly K. Kordzik | 36,571 |
| Ross Spencer Garsson | 38,150 |
| Barry Newberger | 38,286 |

Place Customer
Number Bar Code
Label here

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please change the correspondence address for the above-identified application to:

☐ The above-mentioned Customer Number.

OR

☐ Practitioners at Customer Number

OR

Place Customer
Number Bar Code
Label here

| | | | | | |
|---|----------------------------------|-------|----------------|-----|------------|
| <input checked="" type="checkbox"/> Firm or Individual Name | James J. Murphy | | | | |
| Address | Winstead Sechrest & Minick P.C. | | | | |
| Address | P.O. Box 50784, 1201 Main Street | | | | |
| City | Dallas | State | Texas | Zip | 75250-0784 |
| Country | United States of America | | | | |
| Telephone | (214) 745-5374 | Fax | (214) 745-5390 | | |

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

| | |
|-----------|--------------|
| Name | Jochen Hampe |
| Signature | |
| Date | |

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 23 forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

09902176-071001

PLEASE SEE
& D

Please type a plus sign (+) inside this box → ☐

PTO/SB/81 (02-01)

Approved for use through 10/31/2002. OMB 0651-0035

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it display a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number

Filing Date

First Named Inventor

Stefan Schreiber

Title

Diagnostic Use of Polymorphi

Group Art Unit

Examiner Name

Attorney Docket Number

25481-P001US

I hereby appoint:

☐ Practitioners at Customer Number

OR

☒ Practitioner(s) named below:

| Name | Registration Number |
|----------------------|---------------------|
| James J. Murphy | 34,503 |
| Kelly K. Kordzik | 36,571 |
| Ross Spencer Garsson | 38,150 |
| Barry Newberger | 38,286 |

Place Customer
Number Bar Code
Label here

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please change the correspondence address for the above-identified application to:

☐ The above-mentioned Customer Number.

OR

☐ Practitioners at Customer Number

OR

Place Customer
Number Bar Code
Label here

☒ Firm or
Individual Name

James J. Murphy

Address

Winstead Sechrest & Minick P.C.

Address

P.O. Box 50784, 1201 Main Street

City

Dallas

State

Texas

Zip

75250-0784

Country

United States of America

Telephone

(214) 745-5374

Fax

(214) 745-5390

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name

Silvia Mascheretti

Signature

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 4 forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

PLEASE
& D